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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/557,991	11/22/2005	Paul James Davis	056222-5094	5135

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EXAMINER	
UNDERDAHL, THANE E	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/557,991	DAVIS ET AL.	
	Examiner	Art Unit	
	Thane Underdahl	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *18-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 11/22/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response, with traverse, to the Restriction/Election requirement filed on 09/05/07 is acknowledged. The applicant elected Group I which includes claims 1-17.

The Applicant did not disclose a detailed argument of the traversal. Therefore, the Restriction/Election requirement is therefore made FINAL and the elected species and the claims they include will now be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation of claim 2 that indicates that the enzyme is in a hydrated condition is indefinite. It is unclear if the Applicant means that the enzyme merely retains its water molecules require to maintain its tertiary shape or that the enzyme is not lyophilized or is in an aqueous solution. Clarification is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 101 because they teach a product of nature such as blood. Mammalian blood inherently comprises enzymes, zinc ions and/or a source of ammonium ions that are capable of being released into solution.

Therefore this product of nature anticipates claims 1, 2, 4, and 5.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 8, 9, 12 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshinaga et al (U.S. Patent # 3546070).

These claims are drawn to a composition comprising and enzyme and a source of lactate ions and source of zinc ions and/or a source of ammonium ions. The enzyme is hydrated and can be an oxidase such as a catalase or an oxidase. The composition must be capable of releasing zinc and lactate ions in water. The composition further comprises other components such as sugar alcohols and proteins.

Yoshinaga et al. teach a composition for fermentation that includes an aqueous medium comprising ammonium salts, lactate salts, zinc sulfate (col 1, lines 1-15), proteins from yeast extract (col 3, line 58) and sugar alcohols such as glycerol (col 2, line 25). The composition includes microorganisms that include catalase (col 2, line 46) and an oxidase (claim 1). The addition of lactate salts and zinc sulfate will inherently provide sources of these ions that are soluble in water and can be released in water. Also the

Therefore the reference anticipates claims 1, 2, 4, 5, 8, 9 and 16.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12, 14, and16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshinaga et al. as applied to claims 1, 2, 4, 5, 8, 9, 12 and 16 above and with the following rational in light of Bartnik et al. (U.S. Patent # 5399393).

The description and rejection of claims 1, 2, 4, 5, 8, 9, 12 and 16 are listed in the 35 U.S.C § 102(b) rejection above. Claims 3 limits the ammonium ion comprises ammonium sulfate. Claim 6 and 7 limit the zinc ion to zinc L-lactate. Claims 10 and 11 limit that the composition is sterilized by irradiating such as gamma radiation.

While Yoshinaga et al. teach that their composition may comprise zinc sulfate, ammonium (aqueous ammonia) and lactate (Yoshinaga, col 2 to col 3), they do not specifically teach zinc lactate or ammonium sulfate. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made. One of ordinary skill in the art would recognize that both zinc lactate and ammonium sulfate salts rapidly dissociate in aqueous solutions, becoming independent ions. So one of ordinary skill in the art would recognize that it would not matter if ammonium sulfate or zinc lactate were added to the solution or equimolar amounts of ammonium lactate and zinc sulfate were added to the solution since free ions generated from these salts in solution would remain the same. Therefore since Yoshinaga et al. teach all these ions individually it

would be obvious to add salts that comprise these ions regardless of how the ions are paired as salts, provided that the end result is an equimolar amount of the same ions.

Furthermore while Yoshinaga et al. does not specifically teach that the lactate used in their experiments is L-lactate this would be obvious to one of ordinary skill in the art. A skilled artisan in the art would recognize that L-lactate is the form used in metabolism as supported by Bartnik et al (col 2 lines 45-50). Since Yoshinaga et al. teaches a culture medium for a microorganism, it would be obvious to one of ordinary skill in the art to use L-lactate as opposed to other enantiomers of lactate since it is the most readily metabolized.

Furthermore, while Yoshinaga et al. does teach that their medium is sterilized by steam, they do not teach that it is sterilized by gamma radiation. However this is a product by process limitation. M.P.E.P. § 2113 state "Product by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps". Therefore the product being examined in the claims includes the composition and not the steps used to obtain this composition.

Furthermore, this would be obvious to one of ordinary skill in the art by the time the invention was made. One of ordinary skill in the art would recognize that sterilization can be accomplished by a variety of means and all achieve the same goal of killing unwanted microorganisms. Combining prior art elements according to known methods to obtain predictable results is obvious (KSR International Co. v. Teleflex Inc., 550 U.S. --, 82 USPQ2d 1385 (2007)).

Therefore the references listed above renders obvious claims 1-12, 14, and 16.

Claims 1-12, 14-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshinaga et al. as applied to claims 1-12, 14, and 16 above, and further in view of Savage (U.S. Patent # 5552316).

The description and rejection of claims 1-12, 14, and 16 are listed in the 35 U.S.C § 103(a) rejection above. Claim 15 limits that the composition comprise sodium lactate and 2-acrylamido-2-methyl propanesulphonic acid, ammonium salt (ammonium **AMPS**). While Yoshinaga et al. does teach the addition of sodium lactate and other ammonium salts in their culture medium that do not specifically teach the addition of ammonium AMPS. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Savage.

Savage teaches that polymers of ammonium AMPS are excellent anti-foam agents for fermentation (Savage, col 3, lines 1-4). Since Yoshinaga et al. is utilizing their composition in a fermentation method it would be obvious to one of ordinary skill in the art to add the anti-foam agent of Savage since this is simply the use of a known technique to improve similar compositions for fermentation (KSR International Co. v. Teleflex Inc., 550 U.S. --, 82 USPQ2d 1385 (2007)).

Therefore the references listed above renders obvious claims 1-12, 14-16.

Claims 1-14 and16 rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshinaga et al. as applied to claims 1-12, 14, and 16 above, and further in view of Armenta et al. (U.S. Patent # 4775626).

The description and rejection of claims 1-12, 14, and 16 are listed in the 35 U.S.C § 103(a) rejection above. Claim 13 limits the oxidase to glucose oxidase.

While Yoshinaga et al. teaches a fermentation composition comprising oxidase and glucose they do not specifically teach glucose oxidase. Regardless this would be obvious to one of ordinary skill in the art by the time the invention was made in view of the teachings of Armenta et al. They teach that glucose oxidase protects anaerobic microorganism by scavenging residual oxygen in the anaerobic chamber (Armenta, see Abstract, Description of the Specific Embodiments and col 3, lines 47-50). It would be obvious to combine the teachings of Armenta et al. with Yoshinaga et al. since the addition of glucose oxidase is a known technique to improve an anaerobic fermentation method (KSR International Co. v. Teleflex Inc., 550 U.S. --, 82 USPQ2d 1385 (2007)).

Therefore the references listed above renders obvious claims 1-14 and16.

Claims 1-14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshinaga et al. and Armenta et al. as applied to claims 1-14 and16 above, and in further view of Carlsson (Infection and Immunity, 1980).

The description and rejection of claims 1-14 and16 are listed in the 35 U.S.C § 103(a) rejection above. Claim 17 adds a lactoperoxidase to the composition.

While Yoshinaga et al. and Armenta et al. teach the addition of glucose oxidase to a fermentation composition, they do not teach the addition of lactoperoxidase. However Armenta et al. specifically states that adding glucose oxidase to an anaerobic

fermentation composition as well as a hydrogen peroxide scavenger to reduce the hydrogen peroxide generated by the oxidase.

Carlsson et al. teach that the addition of lactoperoxidase in conjunction with thiocyanate is effective at scavenging hydrogen peroxide in anaerobic conditions. It would be obvious to one of ordinary skill in the art to add lactoperoxidase to their anaerobic fermentation composition since Armenta et al. provides motivation by teaching that the addition of glucose oxidase and a hydrogen peroxide scavenger is effective at protecting anaerobic microorganisms. Carlsson provides a reasonable expectation of success by teaching that lactoperoxidase in conjunction with thiocyanate is an effective hydrogen peroxide scavenger.

Furthermore it would have been obvious to someone skilled in the art to add lactoperoxidase in conjunction with thiocyanate for a composition for use in an anaerobic method since this is a known additive for improving compositions for use in such conditions (KSR International Co. v. Teleflex Inc., 550 U.S. --, 82 USPQ2d 1385 (2007)).

Therefore the references listed above renders obvious claims 1-14, 16 and 17.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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PRIMARY EXAMINER